

AMENDMENTS

Listing of Claims

The following listing of claims replaces all previous listings or versions thereof:

1. (Original) A method for evaluating the risk of irinotecan toxicity in a patient comprising determining the presence of a polymorphism in one or both *UGT1A1* genes of the patient, wherein the polymorphism is in linkage disequilibrium with a *UGT1A1* TA repeat.
2. (Original) The method of claim 1, further comprising amplifying from a nucleic acid sample all or part of 5' flanking region of one or both *UGT1A1* genes to obtain amplification products and analyzing the amplification products for the presence or absence of a polymorphism.
3. (Original) The method of claim 1, wherein the polymorphism is at nucleotide position -3440, -3401, -3279, -3177, -3175, or -3156 from the *UGT1A1* gene transcriptional start site.
4. (Original) The method of claim 1, wherein the number of TA repeats is 5, 6, 7, or 8 TA repeats.
5. (Original) The method of claim 1, wherein the polymorphism is a -3440C>A polymorphism.
6. (Original) The method of claim 1, wherein the polymorphism is a -3401T>C polymorphism.
7. (Original) The method of claim 1, wherein the polymorphism is a -3279G>T polymorphism.
8. (Original) The method of claim 1, wherein the polymorphism is a -3177C>G polymorphism.
9. (Original) The method of claim 1, wherein the polymorphism is a -3175A>G polymorphism.
10. (Original) The method of claim 1, wherein the polymorphism is a -3156G>A polymorphism.

11. (Original) The method of claim 1, wherein determining the presence of a polymorphism in one or both *UGT1A1* genes of the patient comprises determining the nucleotide sequence at position –3156 in one or both genes.

12. (Original) The method of claim 11, further comprising classifying the UGT1A1 activity level in the patient, whereby identification of a guanine residue indicates the patient does not have a low level of activity.

13. (Original) The method of claim 11, further comprising determining the nucleotide sequence at position –3156 of a second *UGT1A1* gene in the patient.

14. (Original) The method of claim 11, further comprising administering irinotecan to the patient if a guanine nucleotide is found at position –3516.

15. (Original) The method of claim 1, further comprising analyzing a glucuronidation rate associated with the polymorphism.

16. (Original) The method of claim 1, further comprising optimizing a dose of irinotecan for administration to the patient.

17. (Original) The method according to claim 1, wherein determining the presence of a polymorphism of a UGT1A1 gene or genes is performed by a hybridization assay.

18. (Original) The method according to claim 1, wherein determining the presence of a polymorphism of a UGT1A1 gene or genes is performed by a sequencing or microsequencing assay.

19. (Original) The method according to claim 1, wherein determining the presence of a polymorphism of a UGT1A1 gene or genes is performed by an allele-specific amplification assay.

20. (Original) The method of claim 1, further comprising administering to the patient irinotecan.

21. (Original) The method of claim 20, further comprising administering to the patient a second agent to reduce excretion of an active irinotecan species through the bile.

22. (Original) A method for evaluating the risk of irinotecan toxicity in a patient comprising: determining the nucleotide sequence at position -3156 in one *UGT1A1* gene of the patient.

23. (Original) The method of claim 22, further comprising classifying the UGT1A1 activity level in the patient, whereby identification of a guanine residue indicates the patient does not have a low level of activity.

24. (Original) The method of claim 22, further comprising determining the nucleotide sequence at position -3156 of a second *UGT1A1* gene in the patient.

25. (Original) The method of claim 22, further comprising administering irinotecan to the patient if a guanine nucleotide is found at position -3516.

26. – 33. (Canceled)